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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,654	06/13/2001	Leanna M. Levine	2842/3	7335

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EXAMINER

WINKLER, ULRIKE

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/880,654

Applicant(s)

LEVINE ET AL.

Examiner

Ulrike Winkler

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 is/are allowed.
- 6) ☒ Claim(s) 1-9, 11 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

The Amendment filed November 13, 2003 in response to the Office Action of November August 11, 2003 is acknowledged and has been entered. Claims 1-11 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claim 10 as lacking antecedent basis for the limitation of "Abu" is **withdrawn in** view of Applicant's amendment to the claim.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 1 and 11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of Applicant's amendment to the claims.

#### ***Claim Rejections - 35 USC § 103***

The rejection of claims 1-9 and 11 under 35 U.S.C. 103(a) as being obvious over Heath et al. (U.S. Pat. No. 5,235,039, IDS), Bromberg (U.S. Pat. No. 4,203,670) and Maeda (Analytical Biochemistry 1979, IDS) in view of Welch et al. (PNAS 1991, IDS) or Blakeslee et al. (Journal of Immunological Methods, 1976) is **maintained** for reasons of record.

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In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant's arguments are that the Heath et al. reference is not suited for high throughput analysis, that Blomberg et al. is entirely devoid of mentioning measuring florescence polarization comprising a protease substrate and that Maeda et al. does not describe the use of fluorescence polarization to measure protease activity. Another argument raised by Applicant is that the Heath et al. reference utilizes additional steps in measuring the proteolytic cleavage of their peptide substrate. Applicants claim language allows for additional step because the claim includes open claim language "comprising" (see MPEP 2111.03).

MPEP 2111.03 The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

Blomberg et al. was cited by the office for the general teaching regarding fluorescence polarization techniques and how the data is captured using such an apparatus. Maeda et al. teaches the use of a single step assay that does not require any process steps such as separation, precipitation or centrifugation, the data can be captured directly from the reaction cuvette. Maeda et al. label large protein substrates with FITC these large molecules tumble in the reaction mixture at very slow rate, as the protease cleaves the substrate the FITC containing molecules will

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have greater movement and will tumble faster in the reaction mixture, this will result in the reaction mixture having a decreased P-value indicating that the protein substrate has been cleaved by the protease. One of ordinary skill in the art would recognize that binding of the substrate to a surface as taught by Heath et al. will prevent the substrate from tumbling in the solution, this is analogous to having the FITC label attached to a large protein so the tumbling of the substrate is slower. Once cleaved by the protease the label is then able to tumble more quickly in the solution, due to the altered Brownian motion, resulting in the decreased P-value.

Therefore, it remains the position of the Office that it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize known substrates for the detection of protease activity and apply the fluorescence polarization technique to determine substrate cleavage which can be obtained directly from the reaction mixture in a single cuvette as taught by Maeda. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the substrate configuration as taught by Heath et al. and apply them to the peptide substrates taught by Welch et al. One would have been motivated to do this in order to develop a single step assay for herpes virus proteases. Optimizing experimental conditions, including the addition of spacers between the amino acid and the binding group or fluorescing group, choosing the fluorescing group so that it minimizes quenching and optimizes signal output, falls within the skills of an ordinary artisan. Blakeslee et al. teaches that DTAF and FITC have identical properties, because of the lower cost involved with DTAF one of ordinary skill in the art would have been motivated to substitute DTAF for FITC in the substrate taught by Heath et al. Therefore, the instant invention is obvious over Heath et al., Maeda et al. and Bromberg in view of Welch et al. or Blakeslee et al.

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### ***Claim Objections***

Claim 10 is objected to because of the following informalities: The claim is objected to because it depends on a rejected claim. Appropriate correction is required.

### ***Conclusion***

Claim 10 is objected to for depending on a rejected claim.

Claim 16 is allowable.

Claims 1-9 and 11 are rejected.


Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [[ulrike.winkler@uspto.gov](mailto:ulrike.winkler@uspto.gov)].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

  
ULRIKE WINKLER, PH.D.  
PRIMARY EXAMINER 9/15/04